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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,235	10/20/2000	James G. Clough	09166/002001	8568

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3728

DATE MAILED: 12/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/693,235	CLOUGH, JAMES G.
	<b>Examiner</b>	<b>Art Unit</b>
	Jila M Mohandes	3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 October 2002.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-23 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

## **DETAILED ACTION**

### ***Request For Continued Examination***

1. The request filed on October 16, 2002 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/693,235 is acceptable and a RCE has been established. An action on the RCE follows.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1, 10 and 18, the limitation "for placement under a toe and not extending under a first metatarsal" is inaccurate, vague and indefinite. It is not clear what structure such language encompasses. The amount the wedge will extend under the toe will depend on the size of the toe of the wearer and will vary from one person to another.

Claims 16 and 17 recites the limitation "the at least one fastener" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in  
(1) an application for a patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent,  
except that an international application filed under the treaty defined in section 351 (a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designate the United States and was published under Article 21 (2) of such treaty in the English language; or

5. Claims 1, 3-5 and 10, 11, 13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Epstein (6,098,319). Epstein '319 discloses an orthopedic appliance, comprising a wedge (16) that can be placed under a toe, the wedge having a top surface (32) that can support the toe and a lower surface (34), wherein an angle of inclination between the top surface and the bottom surface is between 1 and 60 degrees (See Figure 2 embodiment and column 3, lines 38-41).

With respect to claims 4-5, and the material of the wedge, see column 3, lines 30-34.

With regard to claims 7 and 15, adhesive is used to fasten the wedge.

All the functional claim language and statements of intended use do not make an otherwise unpatentable claim patentable. It is believed to be well settled that "recitation with respect to manner in which claimed apparatus is intended to be employed does not differentiate claimed apparatus from prior art apparatus satisfying structural limitations of that claimed," *Ex parte Masham* 2 USPQ2nd 1674. Also *Ex parte Casey* 152 USPQ 235. The law of anticipation does not require that an anticipatory reference teach what the applicant is claiming or has disclosed, but only that the claims "read on" something disclosed in the reference, i.e., all limitations of the claim are found in the reference. See *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 218 USPQ 871 (Fed Cir. 1983). Furthermore, it is only necessary that the reference include structure capable of performing the recited function in order to meet the functional limitations of a claim. See

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*In re Mott*, 557 F.2d 266, 194 USPQ 305 (CCPA 1977). Since the reference device has all of the same structural elements, as noted above, it would clearly seem to be inherently capable of performing the functions as claimed.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 18-23 are rejected under 35 U.S.C. 103(a) as being obvious over Epstein '319. Claims 18-23 are directed to the obvious method of using the orthopedic appliance of Epstein '319.

8. Claims, 1-5, 10-13 and 18-23 are rejected under 35 U.S.C. 103(a) as being obvious over Liley (6,182,380) in view of Rothbart (6,092,314). Liley '380 discloses an orthopedic appliance, comprising a wedge (equalizer pad 11) that is for placement under a toe and not extending under the first metatarsal, the wedge having a top surface adapted to support the toe and a bottom surface. See Figure 9 embodiment and column 5, lines 39-42. Liley '380 does not teach ~~the~~ an angle of inclination between the top surface and the bottom surface. Rothbart '314 discloses an orthopedic appliance, comprising a wedge (60) for placement under a toe, the wedge having a top surface adapted to support the toe and a lower surface, wherein an angle of inclination between the top surface and the bottom surface is between 1 and 60 degrees to better support the foot both statically and dynamically. Therefore, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to make the wedge of Liley '380 with an angle of inclination between the top surface and the bottom surface to be between 1 and 60 degrees to better support the foot both statically and dynamically.

With respect to claims 4 and 5 which further limits the material of the orthopedic appliance, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the orthopedic appliance from different material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 18-23 are directed to the obvious method of using the orthopedic appliance of Liley '380 as modified.

9. Claims 7-9 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the above references as applied to claims 1 and 10 above and further in view of either Brock '927 or Jacoby '046. Liley '380 as modified above discloses all the limitations of the claims except for the orthopedic appliance having a fastener. Each of Brock '927 and Jacoby '046 disclose fastening an orthopedic appliance to the toe of a wearer to better secure and hold the appliance to the toe of the wearer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide fastener to the orthopedic appliance of Liley '380, as taught by each of Brock '927 and Jacoby '314 to better secure and hold the orthopedic appliance to the toe of the wearer.

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10. Claims 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the above references as applied to claims 1 and 10 above and further in view of McMahon et al. (5,881,478). Liley '380 as modified above discloses all the limitations of the claims except for the orthopedic appliance having a concave depression formed in the top surface. McMahon '478 discloses an orthopedic appliance having a concave depression (41) formed in its top surface to better hold and secure the flexible coupling elements. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a concave depression in the orthopedic appliance of Liley '380 to better hold and cradle the toe.

***Response to Arguments***

11. Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shown are orthopedic appliances analogous to applicant's instant invention.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jila M. Mohandesu whose telephone number is 703-305-7015. The examiner can normally be reached on Monday-Friday 7:30-4:00 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 703-308-2672. The fax phone numbers for

the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Jila M. Mohandes  
Examiner  
Art Unit 3728

JMM  
December 10, 2002